November 3, 2017

Boston Scientific Corporation
Elizabeth Lisowski
Principal Regulatory Affairs Specialist
4100 Hamline Avenue North
St. Paul, Minnesota 55112

Re: K172591
Trade/Device Name: Fixed Patient Leads ECG Cable (Model 3153)
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer and Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: October 4, 2017
Received: October 5, 2017

Dear Elizabeth Lisowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172591

Device Name
Fixed Patient Leads ECG Cable (Model 3153)

Indications for Use *(Describe)*
The Fixed Patient Leads ECG Cable is used to transmit signals from patient-connected electrodes or transducers to electrocardiograph recorders/monitors for both diagnostic and monitoring purposes.

ECG cables are supplied non-sterile and are not sterilizable; they are reusable devices and are intended for use by trained operators in a medical environment. Usage is limited to the indications for use of the connected monitoring or diagnostic equipment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

1. GENERAL INFORMATION

Device Common / Usual Generic Name:	ECG Cable
Device Trade Name:	Fixed Patient Leads ECG Cable (Model 3153)
Applicant's Name and Address:	Boston Scientific Corporation 4100 Hamline Avenue North St. Paul, Minnesota 55112-5798 FDA Registration Establishment No. 2124215
Product Code / Regulation Citation:	DSA, Cardiovascular / 21 CFR Part §870.2900 The ECG Cable is a Class II device as defined in 21 CFR Part §870.2900 and has a product code of DSA Panel: 74 Cardiovascular
Contact Name and Information:	Elizabeth A. Lisowski Principal Regulatory Specialist Phone: 651-532-5131 Fax: 651-582-5134 E-mail: beth.lisowski@bsci.com
Owner / Operator:	Boston Scientific Corporation One Boston Scientific Place Natick, Massachusetts 01760 FDA Registration Establishment No: 9912058
Manufacturing Facility:	Affinity Medical Technologies 3545 Harbor Boulevard Costa Mesa, California 92626 FDA Registration Establishment No: 2031044

2. DEVICE

Fixed Patient Leads ECG Cable (Model 3153)

3. PREDICATE DEVICE

Removable Patient Leads ECG Cable (*K132253*; cleared December 16, 2013)

4. DEVICE DESCRIPTION

The BSC Model 3153 ECG Cable is an external device used to transmit ECG signals from electrodes that are affixed to the patient's body to an external BSC programming system display monitor. One end of each leadwire clip is attached to an ECG patient electrode; the other end is affixed / molded into one end of the trunk cable. The trunk cable then plugs into the BSC programming system.

5. INDICATIONS FOR USE

The Fixed Patient Leads ECG Cable is used to transmit signals from patient-connected electrodes or transducers to electrocardiograph recorders / monitors for both diagnostic and monitoring purposes.

ECG cables are supplied non-sterile and are not sterilizable; they are reusable devices and are intended for use by trained operators in a medical environment. Usage is limited to the indications for use of the connected monitoring or diagnostic equipment.

6. DEVICE COMPARISON TO PREDICATE

The BSC ECG cable incorporates substantially equivalent design, packaging, fundamental technology, and Indications for Use as the predicate ECG Cable (Removable Patient Leads ECG Cable; *K132253*). Refer to **Table 1** for a comparison between the BSC Fixed Patient Leads ECG Cable and the BSC Predicate Removable Patient Leads ECG Cable.

Table 1: Comparison between BSC Fixed Patient Leads ECG Cable and BSC Predicate Removable Patient Leads ECG Cable.

Characteristic	Proposed BSC Fixed Patient Leads ECG Cable	Predicate BSC Removable Patient Leads ECG Cable
Indications for Use	ECG Cable is used to transmit signals from patient-connected electrodes or transducers to electrocardiograph recorders / monitors for both diagnostic and monitoring purposes.	ECG Cable is used to transmit signals from patient-connected electrodes or transducers to electrocardiograph recorders / monitors for both diagnostic and monitoring purposes.
Patient Usage	Reusable	Reusable
Sterility	Supplied non-sterile; cannot be sterilized	Supplied non-sterile; cannot be sterilized
Anatomical Sites	Attached to electrodes placed at standard specified locations on chest wall and extremities	Attached to electrodes placed at standard specified locations on chest wall and extremities
Design / Appearance / Functionality		
Functionality	Transmits signals from 5 patient-connected leadwires	Transmits signals from 5 patient-connected leadwires
No. of Leadwires *(Patient Wire)*	5	5
Leadwire / Trunk Cable Joint	Fixed	Removable
Trunk Cable Length *(from edge of yoke to edge of patient clip)*	80±2″	120±6″
Leadwire Length (*each*)	30±2″	40±1.5″
Connector – Patient End	Patient Clip	Patient Clip
Connector – Monitor End	6 pin DIN AAMI	6 pin DIN AAMI

Characteristic	Proposed BSC Fixed Patient Leads ECG Cable	Predicate BSC Removable Patient Leads ECG Cable
Materials	Biocompatible per 10993-1	Biocompatible per 10993-1
Leadwire Colors (IEC 60601-2-27)	White Red Green Black Brown	White Red Green Black Brown
Packaging	Outer labeled box Inner labeled bubble pouch Non-sterile	Outer labeled box Inner labeled bubble pouch Non-sterile

7. PERFORMANCE DATA

Component Qualification, Electrical Device Verification Testing (DVT) (including Electromagnetic Immunity / Electromagnetic Compatibility (EMI / EMC), Electrical Safety, and general functional testing), Biocompatibility Assessment, and a Packaging Assessment were performed to support a determination of substantial equivalence.

Design Verification Testing conducted to support this submission demonstrated that all requirements were met. Component Qualification verified the ability for Affinity to provide ECG Cables that meet BSC mechanical and electrical specifications, as well as functionality / performance requirements. Electrical DVT verified that the Model 3300 Programmer and associated cables, including the proposed ECG Cable, meet system electrical design specifications.

Design Validation Testing conducted on the proposed ECG Cable demonstrated that the cable meets user needs and its intended use. Results of Biocompatibility Testing demonstrated that the ECG Cable is biocompatible for its intended use.

Design Analysis and Evaluation Testing evaluated device robustness and correct implementation of the design intent. Results of the Packaging Assessment demonstrated that Affinity-manufactured ECG Cable box labels meet adhesion, legibility, and indelibility requirements.

Standards applicable to the proposed ECG Cable:

- ANSI/AAMI EC53:2013: ECG trunk cables and patient leadwires
- IEC 60601-1:2005: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014: Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – requirements and tests

Standards used to perform Biocompatibility Testing:

- EN ISO 10993-5:2009: Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

- EN ISO 10993-10:2013: Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

Results of this testing provide reasonable assurance that the proposed device design meets the performance requirements and performs as intended.

8. CONCLUSION

Based on the Indications for Use, technological characteristics, and safety and performance testing, the BSC Fixed Patient Leads ECG Cable has been shown to be appropriate for its Indications for Use and is considered to be substantially equivalent to the predicate BSC Removable Patient Leads ECG Cable cleared by FDA on December 16, 2013 *(K132253)*.